

CLAIMS

What is claimed is:

1. A device for use with a transducer to separate an analyte from a fluid sample, the device comprising a cartridge having:
 - a) a sample flow path;
 - b) a lysing chamber in the sample flow path for lysing cells or viruses to release the analyte therefrom, wherein the lysing chamber contains at least one filter for capturing the cells or viruses from the sample as the sample flows through the lysing chamber, the cartridge includes at least one wall defining the lysing chamber, and the wall has an external surface for contacting the transducer to sonicate the lysing chamber;
 - c) a waste chamber in fluid communication with the lysing chamber via the sample flow path for receiving the remaining sample fluid after the sample flows through the lysing chamber;
 - d) a third chamber connected to the lysing chamber via an analyte flow path for receiving the analyte separated from the sample; and
 - e) at least one flow controller for directing the sample into the waste chamber after the sample flows through the lysing chamber and for directing the analyte separated from the sample into the third chamber.
2. The device of claim 1, wherein the third chamber comprises a mixing chamber for mixing the analyte with one or more reagents.
3. The device of claim 2, wherein the cartridge further includes a reaction chamber in fluid communication with the

mixing chamber for holding the analyte for chemical reaction or optical detection.

4. The device of claim 2, wherein the cartridge further includes:

- i) a reaction chamber in fluid communication with the mixing chamber for amplifying the analyte; and
- ii) a capillary electrophoresis area in communication with the reaction chamber.

5. The device of claim 1, wherein the third chamber comprises a reaction chamber for amplifying the analyte and holding the analyte for optical detection, and wherein the cartridge is in combination with an instrument having a heater for heating the reaction chamber and having at least one optical detector for detecting the analyte.

6. The device of claim 1, wherein the third chamber comprises a reaction chamber for amplifying the analyte, and the cartridge further comprises a capillary electrophoresis area in communication with the reaction chamber.

7. The device of claim 1, wherein the wall is dome-shaped and convex with respect to the transducer.

8. The device of claim 1, wherein the wall comprises a sheet or film of polymeric material.

9. The device of claim 8, wherein the wall has a thickness in the range 0.025 to 0.1 mm.

10. The device of claim 1, wherein the wall has stiffening ribs.

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- 11. The device of claim 10, wherein the ribs extend radially from a central portion of the wall.
- 12. The device of claim 1, further comprising beads disposed in the lysing chamber for rupturing the cells or viruses.
- 13. The device of claim 12, wherein the beads further have a binding affinity for the cells or viruses to be disrupted.
- 14. The device of claim 12, wherein the beads further have a binding affinity for the analyte.
- 15. The device of claim 1, wherein the lysing chamber contains a first set of beads for binding the cells or viruses and a second set of beads for rupturing the cells or viruses.
- 16. The device of claim 1, wherein the cartridge includes a first filter in the sample flow path for filtering coarse material from the sample and a second filter in the lysing chamber, the second filter having a smaller average pore size than the first filter
- 17. The device of claim 16, wherein both the first and second filters are positioned in the lysing chamber, and wherein beads are disposed between the filters.
- 18. The device of claim 17, further comprising a third filter in the lysing chamber, wherein the third filter is spaced from the second filter, and the third filter has a smaller average pore size than the second filter.
- 19. The device of claim 18, wherein the cartridge includes a first set of beads disposed between the first and second

filters and a second set of beads disposed between the second and third filters.

20. The device of claim 19, wherein the average diameter of the
5 beads in the first set differs from the average diameter of the beads in the second set.

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